Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2004 list were published in the Federal Register in February 2004.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to *21CFR Parts 500 to 599* and the related Federal Register notices.

NADA Number: 095-735

This supplemental application provides for revised labeling for the use of a single ingredient monensin Type A medicated articles to make Type C medicated feeds used for the prevention and control of coccidiosis.

Trade Name:	Rumensin® 80
Ingredients:	Monensin sodium
Sponsor:	Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date:	December 12, 2003

21CFR 558.355

NADA Number: 130-435

This supplemental application provides for use of oxytetracycline hydrochloride soluble powder for skeletal marking of finfish fry and fingerlings by immersion.

Trade Name:	OxyMarine™
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Alpharma, Inc.
Approval Date:	December 24, 2003
Status:	Over-the-counter
Route:	Immersion
Species:	Finfish (fry and fingerlings)
Drug Form:	Powder
Concentration:	1 gram oxytetracycline hydrochloride per 2.73 grams of powder
Indications:	For the marking of bony tissues (usually the otoliths) for subsequent indentification.
Tolerance:	21CFR 556.500 Oxytetracycline: A tolerance of 2 parts per million as the sum of tetracycline residues has been previously established for the edible tissues of catfish and salmonids and is now being extended to all finfish.
Withdrawal:	A withdrawal time beyond the grow-out period is not needed.

21CFR 529.1660 & 556.500

NADA Number: 140-338

This supplemental application provides for revision of the susceptibility information for food-animal pathogens listed in the clinical microbiology section of the labeling.

Trade Name:	Naxcel® Sterile Powder
Ingredients:	Ceftiofur sodium
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	December 31, 2003

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 200-346

This supplemental application provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone acetate and estradiol.

Trade Name:	Component® TE-200 with Tylan®
Ingredients:	Trenbolone acetate, estradiol, tylosin tartrate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	January 9, 2004
Status:	Over-the-counter
Route:	Subcutaneous (ear)
Species:	Cattle (steers fed in confinement for slaughter)
Drug Form:	Implant
Concentration:	Each implant contains 200 mg trenbolone acetate, 20 mg estradiol, and 29 mg tylosin tartrate.
Indications:	For increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.739 Trenbolone: Tolerance for residues is not needed. 21CFR 556.240 Estradiol: No residues of estradiol or any of the related esters are permitted in the uncooked edible tissues in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver. 21CFR 556.740 Tylosin: Tolerances are established for residues of tylosin in edible products in cattle as 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days
Patent Number:	5,874,098 Expiration Date: May 28, 2017
Exclusivity:	3 years

21CFR 522.2477

Suitability Petition Action

Number:	04P-0032/CP1
Sponsor:	Pennfield Oil Co.
Petition:	Request permission to file an ANADA for a generic new animal drug chlortetracycline/sulfamethazine which differs from the pioneer product, Aureo S 700®, Alpharma, Inc., NADA 035-805 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Filed on January 20, 2004.

Number:	04P-0058/CP1
Sponsor:	Cross Vetpharm Group, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Butatron®, Cross Vetpharm Group, Inc., NADA 044-756 by the following characteristic(s): The generic product will have a different physical form, powder, whereas the pioneer approved product is a tablet.
Action:	Filed on February 9, 2004.